

Message Text

UNCLASSIFIED

PAGE 01 PARIS 05866 281736Z
ACTION HEW-06

INFO OCT-01 OES-06 ISO-00 EUR-12 /025 W
-----010314 075699 /66

R 281745Z FEB 77
FM AMEMBASSY PARIS
TO SECSTATE WASHDC 0110

UNCLAS PARIS 05866

E.O.11652: N/A
TAGS: OGEN, ETRD, TBIO, FR.
SUBJECT: FDA ADVISORY- DEFECTIVE MEDICAL DEVICE (RECALL
T-045-050-7)

REF. (1) PARIS 4213 ; (2) STATE 38275

1. POST CONTACTED THE FRENCH FIRM SIMMHO, 13 RUE
GUEBWILLER, 67-STRASBOURG-NEUDORF TO DETERMINE IF
CONSIGNEE HAD BEEN ADVISED TO DISCONTINUE SALE OR USE
OF THE RADIOPAQUE PERCUTANEOUS CATHETER INTRODUCER
MANUFACTURED BY USCI, A DIVISION OF C.R. BAND, INC.,
BOX 566, BELLERCA, MASS. 01821.

2. MR. RICHTER, GENERAL MANAGER OF SIMMHO STATED THAT
HE HAD RECEIVED NUMEROUS LETTERS FROM THE US FIRM
CONCERNING THIS MATTER, AND THAT HOSPITALS AND/OR
PHYSICIANS USING THESE PRODUCTS HAD IMMEDIATELY BEEN
NOTIFIED.

3. THE FORMER FRENCH DISTRIBUTOR GAMIDA HAD ALSO BEEN
NOTIFIED BY THE US FIRM.

4. DESPITE MINOR DIFFICULTIES WITH DEVICES NO MAJOR
MALFUNCTIONS REPORTED.
RUSH.

UNCLASSIFIED

NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, SALES, INVESTIGATIONS, RECALLS
Control Number: n/a
Copy: SINGLE
Sent Date: 28-Feb-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977PARIS05866
Document Source: CORE
Document Unique ID: 00
Drafter: n/a
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770069-0444
Format: TEL
From: PARIS
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t1977022/aaaaacds.tel
Line Count: 47
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 92dd60c3-c288-dd11-92da-001cc4696bcc
Office: ACTION HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 1
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: 77 PARIS 4213, 77 STATE 38275
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 27-Oct-2004 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 3260842
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY- DEFECTIVE MEDICAL DEVICE (RECALL T-045-050-7)
TAGS: OGEN, ETRD, TBIO, FR
To: STATE
Type: TE
vdkgvwkey: odbc://SAS/SAS.dbo.SAS_Docs/92dd60c3-c288-dd11-92da-001cc4696bcc
Review Markings:
Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
22 May 2009
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009